

Scient'x Cement Restrictor
510(k) Summary

<u>Date</u>	August 26, 2005	OCT 5 - 2005
<u>Submitter</u>	Scient'x Batiment Calypso Parc Ariane 3 78284 Guyancourt FRANCE	
<u>Contact person</u>	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199	
<u>Trade Name</u>	Scient'x Cement Restrictor	
<u>Common name</u>	Cement restrictor	
<u>Classification name</u>	Class II per 21 CFR section 888.3300	
<u>Product Code</u>	JDK	
<u>Equivalent Device</u>	RABEA™ Cement Restrictor (Signus Medical, K020836) Fortitude™ Cement Restrictor (Spinal Concepts, K031837)	
<u>Device Description</u>	The Scient'x Cement Restrictor is a hollow trapezoidal block with 1mm toothed serrations on opposite sides to prevent migration and has a threaded hole on the superior surface to attach an insertion tool. The parts are machined from PEEK that conforms to ASTM F2026-02. As peek is radiolucent gold wire radiographic markers inserted into small holes and serve as location and orientation markers for radiographs.	
<u>Intended Use</u>	<p>The Scient'x Cement Restrictor is intended as a cement restrictor in orthopedic surgeries such as those involving the femoral canal and tibial plateau in hip stem and total knee replacement.</p> <p>This device is not intended for any spinal indications. The safety and effectiveness of this device when implanted in the spine have not been established.</p>	
<u>Nonclinical Tests</u>	No mechanical tests were performed to support this application.	



OCT 5 - 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Scient'x
c/o Mr. J.D. Webb
Authorized Contact Person
The OrthoMedix Group, Inc.
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K052367
Trade/Device Name: Scient'x Cement Restrictor
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: JDK
Dated: August 26, 2005
Received: September 1, 2005

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's package insert and also as a Warning on the product label:

WARNING: THIS DEVICE IS NOT INTENDED FOR ANY SPINAL INDICATIONS.

THE SAFETY AND EFFECTIVENESS OF THIS DEVICE WHEN IMPLANTED IN THE SPINE HAVE NOT BEEN ESTABLISHED.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

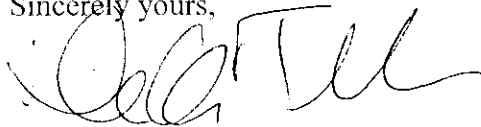
The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Donna-Bea Tillman', written over a horizontal line.

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052367

Device Name: Scient'x Cement Restrictor

Indications for Use:

The Scient'x Cement Restrictor is intended as a cement restrictor in orthopedic surgeries such as those involving the femoral canal and tibial plateau in hip stem and total knee replacement.

This device is not intended for any spinal indications. The safety and effectiveness of this device when implanted in the spine have not been established.

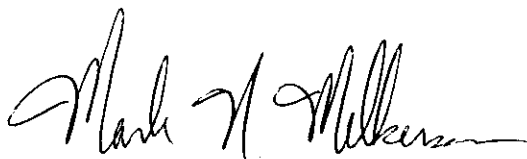
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K052367